



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1154]

Framework for Pharmacy Compounding: State and Federal Roles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting entitled “Framework for Pharmacy Compounding: State and Federal Roles.” At this public meeting, FDA and State representatives will share their perspectives.

Date and Time: The public meeting will be held on December 19, 2012, from 3 p.m. to 5 p.m. Onsite registration will be on a first-come, first-served basis beginning at 2 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993.

Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

If you need special accommodations due to a disability, please contact Steve Morin, FDA Office of Special Health Issues, 301-796-0161, email: [Steve.Morin@fda.hhs.gov](mailto:Steve.Morin@fda.hhs.gov) no later than December 14, 2012.

Contact Person: Patricia Kuntze, Food and Drug Administration, 10903 New H Ave., Bldg. 32, rm. 5322, Silver Spring, MD 20993; [patricia.kuntze@fda.hhs.gov](mailto:patricia.kuntze@fda.hhs.gov).

Streaming Webcast of the Meeting: This public meeting will also be Webcast. Persons interested in viewing the Webcast should use the access connection at <https://collaboration.fda.gov/pharmacycompounding/>. The Webcast will begin on December 19, 2012, at 3 p.m. ET.

If you have never attended a Connect Pro meeting before, test your connection at: [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). Get a quick overview at: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). Adobe, the Adobe logo, Acrobat and Acrobat Connect are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

If for some reason the test page does not work, that is not a definite indicating factor that the actual Webcast will not work. The test link sometimes appears to be broken on some individuals' computers. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

This Webcast will be closed captioned.

Comments: In order to obtain public comment, FDA is also soliciting either electronic or written comments on the issues discussed in section II of this document. The deadline for submitting comments is January 18, 2013.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic

comments to <http://www.regulations.gov>. It is only necessary to send one set of comments.

Identify comments with the docket number found in brackets in the heading of this document. In addition, when submitting comments on issues as outlined in section II of this document, please identify the issue you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The recent outbreak of fungal meningitis associated with drugs produced and sold by New England Compounding Center has raised serious questions about the regulation of pharmacy compounding (Refs. 1 and 2). Historically, regulation of pharmacy compounding has focused on drawing a line between traditional pharmacy compounding and other manufacturing. Generally, day-to-day oversight of traditional pharmacy compounding has been seen as the primary responsibility of the States, which license pharmacies and regulate the practice of pharmacy, while other manufacturing falls under the purview of FDA. Going forward, FDA believes the focus should be shifted from attempting to draw a bright line between traditional pharmacy compounding and other manufacturing to clearly defining traditional pharmacy

compounding that should be primarily overseen by the States and higher risk non-traditional pharmacy compounding that would require compliance with Federal standards. In addition, there are open questions about whether, and to what degree States should enforce Federal standards, what that oversight should look like, and the appropriate level of communication and coordination required to make the system of State and Federal oversight seamless and effective.

FDA recognizes that the States play a critical role in the oversight of traditional pharmacy compounding, which can include compounding a customized medication in response to a prescription by a licensed practitioner based on the identified medical need of a particular patient for the compounded product. However, a category of “non-traditional” compounding has evolved in the last decade that FDA believes requires additional oversight. The Agency is working with Congress to consider new authorities regarding “non-traditional” compounding pharmacies. In recognition of the States’ role, FDA has also reached out to its State partners by inviting representatives from all 50 States to an intergovernmental meeting.

## II. Questions for Comment

The intergovernmental meeting will be an opportunity for the State officials to discuss a variety of issues regarding their views on the role of the FDA and the States in the oversight of compounding including:

- Given existing authorities and resources, are the States currently able to provide the needed oversight of pharmacy compounding and consumer protection?
- What should the Federal role be in regulating higher risk pharmacy compounding such as compounding high-volumes of drugs for interstate distribution? Is there a way to re-balance Federal and State participation in the regulation of pharmacy compounding that would better

protect the public health? What strategies should be developed to further strengthen Federal/State communications?

- Do you see a role for the States in enforcing a Federal standard for “non-traditional” compounding? If so, what role? What factors would affect a decision by your State to take on such responsibility?

The public meeting announced in this document will be held after the intergovernmental meeting described above. FDA is holding this public meeting to share the results of the intergovernmental meeting with interested stakeholders. At the public meeting, FDA representatives and participants from the intergovernmental meeting will summarize the results of the intergovernmental meeting.

### III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. The Fungal Meningitis Outbreak: Could It Have Been Prevented? Statement of Margaret A. Hamburg, M.D., before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

(<http://www.fda.gov/NewsEvents/Testimony/ucm327664.htm>), November 14, 2012.

2. Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak: Margaret A. Hamburg, M.D., before the Senate Committee on Health, Education, Labor,

and Pensions (<http://www.fda.gov/NewsEvents/Testimony/ucm327667.htm>), November 15, 2012.

Dated: November 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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